

EXHIBIT M

Brian J. Flynn, M.D.

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IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

Case No.: 2:13-cv-04457

MDL NO. 2326

VIDEO DEPOSITION OF BRIAN J. FLYNN, MD

August 29, 2014

BOSTON SCIENTIFIC CORPORATION, PELVIC REPAIR SYSTEM PRODUCTS
LIABILITY LITIGATION

Related to

AMBER COMER.

A P P E A R A N C E S:

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<p>1 APPEARANCES: (Cont.)</p> <p>2</p> <p>3 For Witness:</p> <p>4 GREGORY R. PICHE, ESQUIRE</p> <p>5 Singularity Legal, PLLC</p> <p>6 3144 Newton Street</p> <p>7 Denver, Colorado 80211</p> <p>8 (303) 668-4240</p> <p>9</p> <p>10 Also Present: Adam Johnston, Videographer</p> <p>11</p> <p>12 Pursuant to Notice and the Colorado Rules of Civil</p> <p>13 Procedure, the video deposition of BRIAN J. FLYNN, MD called by</p> <p>14 Plaintiff, was taken on Friday, August 29, 2014, commencing at</p> <p>15 7:10 AM at 12631 17th Street, Fifth Floor, Aurora, Colorado,</p> <p>16 before Martha Loomis, Certified Shorthand Reporter and</p> <p>17 Colorado Notary Public.</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p> <p>25</p>	<p>1 THE VIDEOGRAPHER: We are now on the record.</p> <p>2 My name is Adam Johnston. I am a videographer for Golkow</p> <p>3 Technologies. Today's date is August 29, 2014. The time</p> <p>4 is 7:10 a.m. This video deposition is being held at</p> <p>5 12631 East 17th Avenue, Room 5500, Aurora, Colorado. It's</p> <p>6 in the matter of Amber Comer versus Boston Scientific</p> <p>7 Corporation for the U.S. District Court, the Southern</p> <p>8 District of West Virginia. The deponent is Brian J. Flynn,</p> <p>9 M.D.</p> <p>10 Counsel, please identify yourselves for the</p> <p>11 record.</p> <p>12 MR. MCCRARY: My name is Sean McCrary with the</p> <p>13 Andrus Wagstaff firm in Denver representing Plaintiff</p> <p>14 Comer.</p> <p>15 MR. MYERS: Andrew Myers with Wheeler Trigg</p> <p>16 O'Donnell on behalf of Boston Scientific.</p> <p>17 MR. PICHE: Greg Piche here on behalf of the</p> <p>18 deponent.</p> <p>19 THE VIDEOGRAPHER: The court reporter is Martha</p> <p>20 Loomis. She will now swear in the witness.</p> <p>21 P R O C E E D I N G S</p> <p>22 BRIAN J. FLYNN, MD,</p> <p>23 having been duly sworn to state the whole truth, testified as</p> <p>24 follows:</p> <p>25 EXAMINATION</p>
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<p>1 I N D E X</p> <p>2</p> <p>3 VIDEO DEPOSITION OF BRIAN J. FLYNN, MD</p> <p>4 EXAMINATION BY: PAGE</p> <p>5 Mr. McCrary 5, 128</p> <p>6 Mr. Myers 67, 136</p> <p>7</p> <p>8 DEPOSITION EXHIBITS: INITIAL REFERENCE</p> <p>9 Exhibit 1 Notice of Videotaped Deposition 5</p> <p>10 of Brian J. Flynn, MD</p> <p>11 Exhibit 2 Curriculum Vitae, Brian J. Flynn, MD 7</p> <p>12 Exhibit 3 University of Colorado Hospital</p> <p>13 2-28-11 Medical Records, Amber Comer 29</p> <p>14 Exhibit 4 University of Colorado Hospital</p> <p>15 4-8-11 Medical Records, Amber Comer 33</p> <p>16 Exhibit 5 University of Colorado Hospital</p> <p>17 4-6-12 Medical Records, Amber Comer,</p> <p>18 Bates No. 00001 - 00058 36</p> <p>19 Exhibit 6 Pathology of Explanted Transvaginal</p> <p>20 Meshes 49</p> <p>21 Exhibit 7 Polypropylene Vaginal Mesh Grafts</p> <p>22 in Gynecology 53</p> <p>23 Exhibit 8 American Urological Association</p> <p>24 Position Statement, Use of Vaginal Mesh for</p> <p>25 The Surgical Treatment of Stress Urinary</p> <p>Incontinence, BSCM04400016224 75</p> <p>Exhibit 9 University of Colorado Hospital</p> <p>Visit Summary, ComerA_Bolshoun</p> <p>Medical_000108 - 000123 119</p>	<p>1 BY MR. MCCRARY:</p> <p>2 Q. Good morning, Dr. Flynn. My name is Sean McCrary.</p> <p>3 I'm an attorney for one of your patients, Amber Comer.</p> <p>4 Did you receive a copy of a notice of deposition to</p> <p>5 appear today?</p> <p>6 A. I did.</p> <p>7 Q. I got a copy for you right here. We're going to</p> <p>8 mark that as Exhibit 1.</p> <p>9 (Exhibit 1 marked for identification.)</p> <p>10 MR. MCCRARY: Andrew, do you need one?</p> <p>11 MR. MYERS: No, that's fine.</p> <p>12 (BY MR. MCCRARY) Q. Do you see on the second</p> <p>13 page of that document, Doctor, it asked you to bring a couple</p> <p>14 of things with you today?</p> <p>15 A. I do.</p> <p>16 Q. Can we just go through those, and I'll ask you</p> <p>17 whether or not you brought each one of those requests on</p> <p>18 that document.</p> <p>19 A. Okay. So bullet point A, medical records and</p> <p>20 in-hospital records, I have that directly available.</p> <p>21 The University no longer has a paper chart. We</p> <p>22 have electronic charts. So I have my laptop here and access</p> <p>23 to Epic, which is our electronic medical record, EMR. So I</p> <p>24 have all those records readily available, and certainly I can</p> <p>25 print anything if you would like at any point.</p>

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<p>1 I do not have any photographs or slides or 2 questionnaires. I don't have any information sheets. I 3 don't keep any personal records on my patients; everything is 4 a shared chart with the University so I don't have a personal 5 office chart. Everything's the University of Colorado 6 Hospital chart.</p> <p>7 In terms of billing statements and insurance 8 issues, I don't have any copies of that. I have not had any 9 correspondence with the Plaintiff electronically or written 10 communication.</p> <p>11 And with respect to bullet point B, I don't have 12 any emails to Boston Scientific as it pertains to this case 13 or this product, Lynx. I do have a copy of my CV if you'd 14 like me to submit that as an exhibit.</p> <p>15 Q. Sure.</p> <p>16 A. This is an updated copy. And I printed that out 17 this morning, so that is the most recent copy of my CV. 18 Let's see.</p> <p>19 Lastly, bullet point 3, I've never used this 20 product Lynx, so I don't have any, any information for users 21 or instructions to user, patient brochures, or marketing 22 literature from Boston Scientific.</p> <p>23 Q. All right. Thanks, Doctor. And I probably should 24 have asked you this at the outset, but have you ever been 25 deposed before?</p>	<p>1 reconstructive surgery.</p> <p>2 I started out as an assistant professor and was 3 promoted to associate professor at my eighth year. And I'm 4 being considered for full professor.</p> <p>5 My practice is largely in female pelvic medicine, 6 but I do male reconstructive surgery as well.</p> <p>7 Q. Okay. And correct me if I'm wrong. My 8 understanding is that you receive a lot of referrals when 9 other physicians around the region have mesh complications. 10 Is that accurate?</p> <p>11 A. I receive a lot of referrals for a variety of 12 complaints, mesh complications included.</p> <p>13 Q. Would you say that you see more mesh complications 14 than most gynecologists or urogynecologists in this area?</p> <p>15 MR. MYERS: Objection to form.</p> <p>16 A. I see a lot of complications. I'm not familiar 17 with what other people's numbers are. But I know I'm very 18 busy in that part of my practice. It's a significant part of 19 my practice. I've done -- I have an interest in that area.</p> <p>20 (BY MR. McCRARY) Q. Have you ever done any 21 research involving pelvic mesh?</p> <p>22 A. Can you be more specific about research?</p> <p>23 Q. Have you ever performed any studies involving 24 pelvic mesh?</p> <p>25 A. Clinical studies in terms of prospective randomized</p>
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<p>1 A. I have.</p> <p>2 Q. And so you're familiar with the process, and that 3 you need to wait for me to finish before you answer? And if 4 defense -- Defense Attorney has an objection you need to 5 let him get that out there and the same with your attorney, 6 before you give your answer?</p> <p>7 A. Yes. I'm familiar with the process.</p> <p>8 Q. Okay. In that case, why don't we start by just 9 taking a look at your CV here. Is this the only copy you 10 brought with you?</p> <p>11 A. I have an electronic copy right in front of me as 12 well.</p> <p>13 Q. I'll go ahead and mark it and that way we'll both 14 get a copy, and I'll let you look at that as you go. 15 (Exhibit 2 marked for identification.)</p> <p>16 Q. And I just wanted you to give us a brief summary 17 of your background, and how you ended up as a physician here 18 today.</p> <p>19 A. Well, I'm Dr. Brian Flynn. And I am the co- 20 director of female pelvic medicine reconstructive surgery at 21 the University of Colorado. I'm associate professor here of 22 surgery and urology.</p> <p>23 And I've been a faculty member here for more than 24 12 years. I came here in 2002 after finishing my fellowship 25 at Duke University in female pelvic medicine and</p>	<p>1 studies or industry sponsored studies, no. In terms of 2 retrospective case series, yes, looking at my own experiences 3 with mesh.</p> <p>4 I've looked at my experience using TVT Secur is 5 one product that I've written about. And I've published 6 videos on TVT Abbrevio. I have published a video on Prolift 7 is another product that I've published a video on.</p> <p>8 And with respect to mesh complications, I've 9 written about that. I've written two major articles. One 10 was an update for the American Urologic Association. And 11 another article was a recent article in 2013 I believe in the 12 International Urogynecology looking at complications from 13 midurethral slings.</p> <p>14 Most of my research is retrospective case series. 15 It's not bench work. I've never done any laboratory work or 16 bench science, or any kind of biomaterial scientific research 17 on any of these products.</p> <p>18 Q. So does that then mean that you're essentially 19 going back and looking at the cases that you've seen, and 20 quantifying how often you see certain occurrences with pelvic 21 mesh? Is that accurate?</p> <p>22 A. Yes, that's accurate.</p> <p>23 Q. Okay. And you mentioned that you did a video. 24 What were you, what was the purpose of the video? Was it 25 a training video?</p>

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<p>1 Q. Who specifically?</p> <p>2 A. I've worked with Dr. Karlotta Davis. I've worked</p> <p>3 with Dr. Jaime Arruda. All my residents and fellows, they're</p> <p>4 all in training. I've trained over 25 residents and seven</p> <p>5 fellows.</p> <p>6 I've worked with people in all the departments,</p> <p>7 really. That's one of our roles here. We collaborate pretty</p> <p>8 actively with a number of the divisions and departments.</p> <p>9 Q. And do you use pelvic mesh today?</p> <p>10 A. I do.</p> <p>11 Q. What products do you use?</p> <p>12 A. I use a variety of products. I use mesh for</p> <p>13 sacrocolpopexy. I use the American Medical Systems' IntePro</p> <p>14 mesh and also Boston Scientific's Upsilon mesh. And then</p> <p>15 with respect to transvaginal cases, I don't use any</p> <p>16 transvaginal mesh prolapse kits, but I do midurethral slings.</p> <p>17 Q. And what sling do you use?</p> <p>18 A. I use the TVT Exact product and the Boston</p> <p>19 Scientific Advantage Fit product.</p> <p>20 Q. And does your decision as to which of those</p> <p>21 products you use, is that a patient specific thing?</p> <p>22 A. That, and a Hospital decision making. The hospital</p> <p>23 has a products committee. And so a lot of this is determined</p> <p>24 on what the hospital has available to the physicians.</p> <p>25 Q. How long have you been doing female reconstructive</p>	<p>1 on some ProteGen cases. But I was not the attending</p> <p>2 physician for that.</p> <p>3 Q. Do you know anything about how medical devices used</p> <p>4 to treat incontinence are cleared by the FDA?</p> <p>5 A. I'm familiar that there's different processes, some</p> <p>6 more rigorous than others.</p> <p>7 Q. And is that your -- is that the gist of your</p> <p>8 understanding of that process?</p> <p>9 MR. MYERS: Objection to form.</p> <p>10 (BY MR. McCRARY) Q. It's that it's basic --</p> <p>11 A. You have to be more specific on that.</p> <p>12 Q. Do you understand that there's a difference between</p> <p>13 a product being approved by the FDA and being cleared by the</p> <p>14 FDA?</p> <p>15 A. Yes. There's the 510(k) process and the 522</p> <p>16 process. And the different products, depending on which</p> <p>17 schedule they are, might have more investigation than others.</p> <p>18 Q. And with regards to pelvic mesh in general, is it</p> <p>19 your understanding that those products have all been cleared</p> <p>20 through the 510(k) process?</p> <p>21 A. I can't speak of all of the products. I'm</p> <p>22 familiar with the products that I use and how they're</p> <p>23 approved.</p> <p>24 I think it's important for physicians to understand</p> <p>25 the research behind the products that they're using. But</p>
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<p>1 surgery, pelvic reconstructive surgery?</p> <p>2 A. Not including my residency and fellowship, more</p> <p>3 than 12 years.</p> <p>4 Q. Okay. And have you used vaginal mesh during that</p> <p>5 entire 12 years?</p> <p>6 A. Yes.</p> <p>7 Q. Okay. When you were in residency, did they teach</p> <p>8 you how to use vaginal mesh?</p> <p>9 A. Yes.</p> <p>10 Q. Was vaginal mesh a new thing at that time?</p> <p>11 A. It was relatively new. 1998 was when Ulf Ulmsten</p> <p>12 introduced the TVT to the United States, and I probably</p> <p>13 started performing that in around '99 or 2000.</p> <p>14 Q. And is that the, that's the product that you</p> <p>15 learned to use, or the procedure?</p> <p>16 A. The TVT was the first product really involving</p> <p>17 pelvic floor mesh. And yes, I used that product as a</p> <p>18 resident and as a fellow, and was -- used it early in my</p> <p>19 practice here.</p> <p>20 Q. Have you ever used the ProteGen device?</p> <p>21 A. I've seen some of those cases as a resident, but I</p> <p>22 didn't actively participate in that, and I've never used that</p> <p>23 independently in my own practice.</p> <p>24 But from around '95 to '98 we had a doctor, Wen</p> <p>25 Yap, who was one of my mentors, who I may have assisted him</p>	<p>1 there's too many products out there for me to comment on</p> <p>2 how all of them are approved.</p> <p>3 Q. Do you think any pelvic mesh products have ever</p> <p>4 been approved through the premarket approval process?</p> <p>5 A. You mean the 510(k) process? Is that considered</p> <p>6 premarket?</p> <p>7 Q. No. That's actually, that's two different things,</p> <p>8 which is why I'm asking that question.</p> <p>9 A. I don't know the exact specifics then. I know</p> <p>10 that, you know, I know that there's different processes and</p> <p>11 what they're called. And what -- the FDA looks at them. I'm</p> <p>12 not exactly familiar with the process.</p> <p>13 Q. So you don't consider yourself an FDA expert?</p> <p>14 A. No, certainly not.</p> <p>15 Q. Have you ever worked with the FDA?</p> <p>16 A. Yes.</p> <p>17 Q. And have you ever worked with the FDA in the</p> <p>18 capacity of pelvic mesh?</p> <p>19 A. No.</p> <p>20 Q. Okay.</p> <p>21 A. I mean, I've written an update and a response to</p> <p>22 the FDA. I've interviewed the FDA when I wrote the American</p> <p>23 Urologic Association update. I had conversations with them.</p> <p>24 But I was not working for them. I was</p> <p>25 interviewing them in trying to better understand the public</p>

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<p style="text-align: right;">Page 50</p> <p>1 Have you ever seen evidence of either of those</p> <p>2 things in your practice?</p> <p>3 MR. MYERS: Objection to form.</p> <p>4 A. I'm not familiar with this article at all, Sean. I</p> <p>5 mean, I have only had a few minutes to really review. So I'm</p> <p>6 not going to comment on this article.</p> <p>7 (BY MR. McCRARY) Q. Okay. So you have no</p> <p>8 opinions one way or another?</p> <p>9 A. No. This article's not even published. It doesn't</p> <p>10 say what journal it's in. It doesn't say what year. It</p> <p>11 says, Accepted abstract. It's not peer reviewed as far as I</p> <p>12 know. So I'm not going to make any comment on this article.</p> <p>13 If you want to ask me about pathology on Amber,</p> <p>14 I'm happy to ask -- answer questions. I did look at the</p> <p>15 pathology reports for Amber Comer.</p> <p>16 Q. Okay. Let's talk about that.</p> <p>17 You looked at pathology for Ms. Comer. And I</p> <p>18 assume that the pathology was done on the sling that you took</p> <p>19 down and removed?</p> <p>20 A. There was the pathology from Dr. Davis' surgery I</p> <p>21 guess on April 11, and then another pathology report from the</p> <p>22 surgery I did. And that report was dated September 8 I guess</p> <p>23 when it was completed, but that's from surgery on</p> <p>24 September 6.</p> <p>25 Q. Okay. And were there any significant findings in</p>	<p style="text-align: right;">Page 52</p> <p>1 already -- have an attorney before their explant surgery,</p> <p>2 and we're asked to send that specimen. So we send that</p> <p>3 because we're asked to do that.</p> <p>4 And we are trying to learn from this. I've looked</p> <p>5 at the microbiology of meshes here at the University of</p> <p>6 Colorado, but I've never looked at the pathology; I haven't</p> <p>7 organized any kind of retrospective review in those regards.</p> <p>8 Q. So when you say you've looked at the microbiology,</p> <p>9 does that mean you've studied things like tissue ingrowth?</p> <p>10 A. Tissue ingrowth would be considered more under the</p> <p>11 realm of pathology. Microbiology would be specifically</p> <p>12 looking at organisms we could possibly culture from the mesh.</p> <p>13 Q. Have you found evidence of bacteria or other</p> <p>14 organisms in meshes that you've studied?</p> <p>15 A. Yes.</p> <p>16 Q. Do you believe that the way that the particular</p> <p>17 type of mesh is woven has something to do with the presence</p> <p>18 of bacteria in the mesh?</p> <p>19 A. I'm not going to comment on that. All I can say is</p> <p>20 that I've seen bacteria in some of the meshes that we've</p> <p>21 explanted. I can tell you what those organisms are.</p> <p>22 How they end up there I don't know, and whether</p> <p>23 that's related to the designs of meshes, that's something a</p> <p>24 materials scientist might know. But I'm not familiar with</p> <p>25 that.</p>
<p style="text-align: right;">Page 51</p> <p>1 either of the pathologies that were performed either after</p> <p>2 Dr. Davis' surgery or after yours?</p> <p>3 A. The April 2011 surgery, Dr. Davis' surgery was for</p> <p>4 gross examination. It mentions that there's skeletal muscle</p> <p>5 and fibroconnective tissue, negative for inflammation, no</p> <p>6 other abnormality.</p> <p>7 That's a typical report that we receive at the</p> <p>8 University of Colorado Hospital on mesh excisions that</p> <p>9 happened early. I would consider this early.</p> <p>10 Mesh excisions that come later tend to show some</p> <p>11 inflammation. On the September report it said, "Foreign</p> <p>12 material with minimal chronic inflammation," so there was</p> <p>13 some inflammation, but it was considered minimal.</p> <p>14 That's about the extent of the pathological</p> <p>15 analysis that -- that we received from our pathological</p> <p>16 department.</p> <p>17 Q. Is the lack of inflammation significant in any way</p> <p>18 clinically?</p> <p>19 A. I think this is a very new science so we don't</p> <p>20 really understand how to interpret these pathology reports.</p> <p>21 I don't think pathologists have any standards on how to</p> <p>22 prepare the reports, and urologists, urogynecologists are not</p> <p>23 familiar with how to interpret the reports.</p> <p>24 We send the reports because they're often requested</p> <p>25 by the Plaintiff's attorneys. Many of these patients have</p>	<p style="text-align: right;">Page 53</p> <p>1 Q. Could it be related to the design of the meshes?</p> <p>2 MR. MYERS: Objection to form.</p> <p>3 A. I don't know the answer to that.</p> <p>4 (BY MR. McCRARY) Q. Okay. I just want to show</p> <p>5 you. I'm going to mark Exhibit 7. I just want to know if</p> <p>6 you've ever read this.</p> <p>7 (Exhibit 7 marked for identification.)</p> <p>8 A. I don't believe I've read this specific</p> <p>9 publication. I am familiar with Dr. Ostergard and his work.</p> <p>10 But I don't think I've read this publication.</p> <p>11 Q. And the reason I ask is because I want to know your</p> <p>12 opinion on something that he talks about on the third page of</p> <p>13 this thing.</p> <p>14 I wish we had more time. But since we're so</p> <p>15 limited I'm just going to specifically point you to the part</p> <p>16 I'm interested in, which is page 964 on the right column.</p> <p>17 It's the second full paragraph that starts with "Given</p> <p>18 that polypropylene." Do you see that?</p> <p>19 A. Yes.</p> <p>20 Q. It says, "Given that polypropylene is not inert</p> <p>21 within the human body, that mesh shrinkage of up to</p> <p>22 20 percent to 50 percent occurs, that large pore size is</p> <p>23 important for fibrous tissue ingrowth and mesh</p> <p>24 incorporation into host tissues, that surface area is</p> <p>25 directly related to subsequent infection, and that</p>

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